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#### (54) Title: FOAMABLE FORMULATION AND FOAM

#### (57) Abstract

There is described a foamable formulation comprising a foamable carrier and an active ingredient which may be admixed with the carrier or packaged separately and dispersed into the carrier during the foaming process. Alginate gel is a preferred foamable carrier. The foam produced from such a formulation, and a foam sheet produced by drying the foam, also form part of the invention. The formulation, foam and foam sheet are especially useful for medical applications, for example in treating burns. An apparatus to store the components of the formulation and to generate the foam is also described.

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3	The present invention is concerned with a foamable
4	formulation and the foam formed therefrom.
5	
6	A wide variety of gels, creams, ointments, lotions etc
7	are available for application to a body surface. The
8	exact content of such compositions generally depends
9	upon the purpose of application which may be, for
10	example, to clean a body surface, to promote healing of
11	any wound or injury, to prevent an exposed area of the
12	body from drying out, to prevent infection etc. In
13	certain circumstances the composition may include an
14	active ingredient which is administered to the patient
15	by application of the composition.
16	
17	One example of a commercially available gel in
18	INTRASITE™ produced by Smith & Nephew Ltd. This
19	hydrogel contains hydrated carboxymethylcellulose as
20	its main ingredient, and is applied to wounds in gel
21	form as a primary treatment in order to clean the
22	exposed surface by aiding removal of cell debris, dirt
23	etc. In addition to acting as a sloughing agent, the
24	gel also keeps the wound from drying out, thereby
25	promoting healing.

"Foamable Formulation and Foam"

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1 Another example of a gel suitable for use on a wound 2 dressing is described in EP-A-0586260 of Courtaulds 3 Fibres Ltd. The gel disclosed is an alginate gel having an alginate content of 2 to 11 percent by 5 weight. 6 7 . Viewed from one aspect, the present invention provides 8 a formulation for application to a body surface as a 9 foam, said formulation comprising an active ingredient 10 and a foamable, preferably physiologically acceptable, 11 The active ingredient(s) may be present as an 12 integral part of the formulation, or may be held 13 separately to other ingredients of the formulation, 14 being combined therewith during formation of the foam. 15 Optionally, the formulation may also comprise a foaming 16 agent (for example a surfactant) which is capable of 17 promoting production of a foam structure. 18 19 In one embodiment, the present invention provides a, 20 physiologically acceptable (preferably pharmaceutically 21 acceptable), foamable carrier and an active ingredient 22 packaged separately thereto which is admixed with the 23 foamable carrier during the foaming process. 24 25 The term "active ingredient" is used herein to refer to 26 any agent which affects the metabolism or any metabolic 27 or cellular process of the patient (including growth factors nutrients and living cells), promotes cleaning 28 29 of the area to which it is applied (for example aids 30 removal of a debris, dirt, bacteria, malodours and the 31 like), combats infection, hypergranulation, 32 inflanmation and/or aids healing. 33 34 The term "foamable carrier" refers to any ingredient 35 which is compatible with the active ingredient and 36 which is capable of forming a foam. Conveniently the

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foamable carrier does not affect the function of the 1 active ingredient in a detrimental manner. Desirably 2 the foamable carrier is non-irritant when maintained in 3 contact with a body surface for several hours. 4 foamable carrier may be a gel, for example an alginate 5 gel. 6 7 The foam produced may be maintained on the body area, 8 to form a protective covering, for example over a 9 Additionally, the foam may deliver the active 10 ingredient, preferably in a controlled release manner. 11 In one embodiment the foam acts as a transdermal 12 delivery system. The foam may be exposed to the 13 atmosphere so that it dries into a coating, or may be 14 15 covered by conventional dressings. 16 As an example, the foam may be used to treat 17 dermatological conditions (including psoriasis, atopic 18 and allergic eczema). It may be convenient in this 19 20 embodiment for the foam to deliver an active ingredient normally used to alleviate such conditions, for example 21 22 a steroid such as hydrocortisone. 23 In another embodiment the foam may be used to treat 24 burns or scalds, including sunburn. 25 26 27 In another embodiment the foam may be applied cosmetically, and for example may include skin 28 29 moisturising agents, nutrional agents and growth factors suitable to promote skin regeneration. 30 intended for cosmetic use may include colorants or 31 pigments so that the foam may be applied to the skin as 32 a cosmetic or to disquise any blemishes in the skin. 33 34 The foam may be used prophylactically. In particular a 35 foam containing a UV blocking agent may be applied to 36

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1 exposed areas of the skin to protect it from the 2 effects of the sun. 3 4 The formulation of the invention is applied to the body 5 site of interest in the form of a foam and it is 6 therefore essential that the composition undergoes a 7 foaming process before application to the body. 8 foaming process gas is forced into or is formed within 9 the formulation to entrap small bubbles of gas therein, thereby forming the foam. Any suitably gas or gas 10 11 producing system can be used to produce the foam. 12 Mention may be made of butane and nitrous oxide, but 13 other gases are also suitable. Conveniently the foam 14 may be produced by conventional means such as by using 15 aerosol technology. 16 17 The formulation according to the present invention may 18 be stored in any convenient container until required. 19 Generally, the container will be designed to preserve 20 the sterile nature of the formulation. Conveniently 21 the container will be provided with means to foam the 22 composition when required. 23 24 Thus the present invention also provides an apparatus 25 which produces a physiologically acceptable foam as 26 described above. Generally, the foam will be produced 27 from sterile ingredients. 28 29 Viewed from another aspect, the present invention 30 provides a closed container, containing therein a formulation as described above, said container being 31 32 capable of expelling said formulation in the form of a 33 For example, the container may be an aerosol 34 canister, containing a pressurized gas which in use

causes production of the foam. Alternatively, the gas

may be produced by a chemical reaction when two

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1	different ingredients (for example contained in two
2	portions of a sachet) are admixed together. In one
3	embodiment the closed container has separate reservoirs
4	for the foamable carrier and the active ingredient.
5	Thus, the foamable carrier and the active ingredient
6	are stored separately during storage and are admixed
7	together in suitable proportions during the foaming
8	process.
9	
10	The present invention thus provides an apparatus to
11	produce a foam for application to a body surface, from
12	a formulation as defined above, said apparatus
13	comprising:
14	
15	a. a closed container having
16	
17	<ul><li>i) a reservoir containing said foamable carrier;</li></ul>
18	
19	ii) a reservoir containing said active
20	ingredient; and
21	
22	b. foaming means to produce a foam from said foamable
23	carrier.
24	
25	Optionally a foaming agent may be mixed with the
26	foamable carrier.
27	
28	Prior to the foaming process, the foamable carrier is
29	preferably in the form of a gel. The gel may be
30	sterilised and this is generally desirable where the
31	foam is intended for medical use. Usually,
32	sterilisation will take place by autoclaving the
33	formulation, since this is currently the most economic
34	means of achieving sterilisation. Autoclaving at
35	temperatures of from 100°C to 125°C for under ½ hour is
36	normally sufficient. Generally, the autoclaving

1 process should be as mild as possible, whilst being 2 sufficient to sterilise the formulation. For example, autoclaving at temperatures of about 121°C for 15-20 3 minutes is acceptable. The autoclaved formulation may 4 5 then be foamed when cool. It is also possible, 6 however, to sterilise the formulation by other means, 7 for example by  $\gamma$ -irradiation or e-beam irradiation. 8 has been found that autoclaving the gel may cause the 9 MW of the foamable carrier to be slightly reduced. 10 Consequently it may be desirable to select a foamable 11 carrier having a higher MW than that ultimately 12 required. 13 14 The foam forms an air-tight cover around any wound or 15 injury to which it is applied, and this prevents that 16 area from drying out and may also combat infection. 17 The advantages of applying a topical product in the 18 form of a foam include: 19 20 1. Easy rapid application, 21 2. Conforms to surface irregularities, 22 3. Insulates the wound, 23 4. Cools the tissues, 24 5. Offers antibacterial action to prevent 25 infection, 26 6. Biocompatibility with tissue, 27 7. Suitable for use as a vehicle for the 28 administration of pharmaceutical agents, 29 and/or 30 8. Maintains a moist environment. 31 32 It has been observed that the foam produced from the 33 formulation of the present invention may subside over a 34 period of time (for example 3 to 24 hours, especially 6 35 to 12 hours) as some of the gas entrapped in the foam 36 structure escapes. The foamed formulation gradually

dries to produce a foam (i.e. closed cell) sh et which 1 still retains a basic foam structure and which may 2 cover the site to which the foam was applied. 3 foam sheet can be left in place as a protective cover 4 over a wound, may be used to deliver an active 5 ingredient to the site, etc. It is possible to produce 6 the sheet separately as a dressing for a wound or 7 injury for direct application in that form. 8 sheet is therefore a yet further aspect of the present 9 invention. 10 11 Generally, the formulation of the present invention 12 will be applied directly to the body site of interest 13 in the form of a foam, the foam being produced from any 14 suitable device (such as an aerosol) immediately before 15 application. It is, however, possible for a quantity 16 of the foamed formulation to be produced and then 17 applied onto the body site by any suitable means, for 18 example by hand or by spatula. This method may be 19 required for wounds having a narrow opening. 20 21 As stated above, the foam may also be produced on a 22 suitable surface and then dried to produce the foam 23 sheet described above. Generally, the production of 24 the sheet will take place under sterile conditions. 25 The sheet may be divided into a convenient size and may 26 be packaged. Optionally the foam sheet may be produced 27 on contoured surface so that it is moulded to a pre-28 determined shape. 29 30 It has further been observed that where the foam is 31 covered with an airtight cover (for example a plastics 32 backing) the foam structure is maintained, without 33 collapsing to a foam sheet. Covering the freshly 34 produced foam with a plastics cover (for example a 35 plastics film or a plastics bag) may be desirable in 36

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1 circumstances where the bulk of the foam is to be 2 retained. 3 4 Examples of suitable foamable carriers for use in the 5 composition of the present invention include (but are not limited to) alginate and derivatives thereof, 6 7 carboxymethylcellulose and derivatives thereof, 8 collagen, polysaccharides (including, for example, 9 dextran, dextran derivatives, pectin, starch, modified 10 starches such as starches having additional carboxyl 11 and/or carboxamide groups and/or having hydrophillic 12 side-chains, cellulose and derivatives thereof), agar 13 and derivatives thereof (such as agar stabilised with 14 polyacrylamide), polyethylene oxides, glycol 15 methacrylates, gelatin, gums such as xanthum, guar, 16 karaya, gellan, arabic, tragacanth and locust bean gum. 17 Also suitable are the salts of the aforementioned 18 carriers, for example, sodium alginate. Mixtures of 19 any of the aforementioned carriers may also be used, as 20 required. 21 22 Preferred foamable carriers include alginate, 23 carboxymethylcellulose, the derivatives and salts 24 thereof and mixtures of any of these. Alginate (the 25 derivatives or salts thereof, such as sodium and 26 calcium alginate) are especially preferred. 27 carriers having a molecular weight of from 10,000 to 28 200,000 kDa are preferred, especially over 100,000 kDa, 29 for example 150,000 to 200,000 kDa, may be used. 30 31 The formulation may further comprise a foaming agent, 32 which promotes the formation of the foam. Any agent 33 having a surfactant character may be used. 34 surfactants may be cationic, non-ionic or anionic. 35 Examples of suitable foaming agents include cetrimide, 36 lecithin, soaps, silicones and the like. Commercially

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1	available surfactants such as tween are also surtable.
2	Cetrimide (which additionally has an anti-bacterial
3	activity) is especially preferred.
4	
5	The formulation of the present invention (and thus the
6	foam) may be used to deliver pharmaceutically active
7	agents, in particular to deliver such agents in a
8	controlled release manner. Mention may be made of:
9	
10	Antiseptics, Antibacterials and Antifungal agents,
11	such as Chlorhexidine, acetic acid, polynoxylin,
12	povidone iodine, mercurochrome phenoxyethanol,
13	acridene, silver nitrate, dyes eg brilliant green,
14	undecanoic acid, silver sulphadiazine, silver
15	proteins and other silver compounds,
16	metronidazole, benzaclonium chloride;
17	•
18	Nutritional agents, such as vitamins and proteins;
19	
20	Growth factors and healing agents, including
21	Ketanserin a serotonomic blocking agent;
22	
23	Living Cells;
24	
25	<pre>Enzymes include streptokinase and streptodormase;</pre>
26	
27	<pre>Elements - zinc, selenium, cerium, copper,</pre>
28	manganese, cobalt, boron, arsenic, chromium
29	silver, gold, gallium;
30	
31	<pre>Charcoal;</pre>
32	
33	Desloughing and Debriding agents such as
34	hypochlorite and hydrogen peroxide;
35	
36	Astringents including potassium permanganate;

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1	Antibiotics exemplified by neomycin and framycetin
2	sulphate, sulfamylon, fusidic acid, mupirocin,
3	bacitracin, gramicidin.
4	
5	A particularly convenient way of presenting metal ions
6	(for example silver or calcium ions) is via a glass
7	composition. The glass may be ground into particle
8	form and then incorporated into the formulation of the
9	present invention. Optionally the glass is capable of
10	sustained or delayed release of the metal ions.
11	Reference may be made to WO-A-90/08470 of Giltech Ltd
12	which describes a suitable glass composition for
13	delivering silver ions. Thus, a preferred embodiment
14	of the invention is a formulation as described above
15	wherein particles of a metal ion (preferably silver
16	and/or calcium ion) releasing glass are admixed into
17	the formulation during the foaming process.
18	
19	Other preferred pharmaceutically active agents include
20	Chlorhexidine, povidone iodine and cetrimide.
21	
22	In addition the formulation of the present invention
23	may further comprise other conventional additives such
24	as plasticisers and humectants (such as glycerol,
25	propane-1,2-diol, polypropylene glycol and other
26	polyhydric alcohols), free radical scavengers to
27	stabilise against the effects of sterilisation by
28	irradiation, viscosity-adjusting agents, dyes and
29	colorants, and the like.
30	
31	Particularly preferred formulations of the present
32	invention include:
33	
34	1. Alginate/cetrimide

- alone or with chlorohexidine or povidone iodine 35 or other agents. 36

1		<u>Uses</u>
2		<ul> <li>a. Hand and body washing (including scalp</li> </ul>
3		shampoo);
4		<ul> <li>Topic agents for skin carriage sites and</li> </ul>
5		wounds.
6		
7	2.	Alginate/cetrimide/calcium and silver ion
8		releasing glass (eg Arglaes™)
9		- alone or with other agents
10		The calcium released from the glass will stabilise
11		the alginate by forming the insoluble calcium
12		salt.
13		
14		Uses
15		a. Silver is effective against gram negative
16		species eg Proteus, E Coli, Pseudomonas & :
17		Klebsiella aerobacters;
18		
19		b. Cetrimide is a broad spectrum antibacterial
20		and antifungal agent, most effective against.
21		gram positive species eg Staphylococcus
22		epiderimis and aureus (wounds are generally
23		infected on a 50:50 basis with gram positive
24		or negative species); and
25		
26		<ul> <li>c. sloughy wounds, granulating or</li> </ul>
27		epithilialising wounds, black necrotic
28		tissue, clinically infected wounds,
29		malodorous wounds and burns and scalds and as
30		a haemostat.
31		
32	3.	Hydrogel foams in general
33		
34		eg Carboxymethylcellulose
35		
36		eg Gelatin - preformed foam could provide an

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1 improved presentation for burn coverings, 2 temporary soft tissue implants, etc. 3 4. Mixtures 4 5 eg Alginate/collagen mixtures. 6 7 Alginates are particularly preferred as the foamable 8 carrier in the formulation of the present invention. 9 Alginates are especially useful for application to 10 wounds since the alginate promotes the healing process and is itself slowly absorbed and metabolised in the 11 12 body. Sodium alginate is soluble whereas calcium alginate is insoluble. In the present invention 13 14 therefore it is desirable for a careful mixture of 15 sodium and calcium alginate to be produced, the exact ratio being altered in accordance with the desired 16 17 characteristics of the foam. An alginate-based foam 18 may therefore be easily removed simply by washing away 19 in saline. Commercially available alginates suitable for use in the present invention include Manucol DMF, 20 Manucol LKX, and Keltone™ for example Keltone HV™ which 21 22 is a finely ground fibrous sodium alginate suitable for High molecular weight 23 use in food preparations. alginates are preferred, for example these having a 24 molecular weight of 50,000 kDa or above, for example 25 100,000 to 200,000 kDa. 26 27 The present invention further provides the use of a 28 29 formulation for production of a foam suitable for medical or veterinary purposes, especially for the 30 controlled released delivery of the active ingredient. 31 32 For example, the present invention provides the use of 33 a formulation to produce a foam suitable for 34 application to wounds or injuries, especially burns. 35 The invention further provides the use of a formulation 36

13

1 to produce a foam which delivers an active ingredient, 2 such as a cleaning agent or a medicament to the body. For example, the foam produced may be used as a soap alternative for doctors or other medical staff to clean 4 5 their hands before seeing a patient. Use of the foam could eliminate the need for washing in water. 6 7 8 Additionally, the present invention provides the use of the foam itself for application (in particular topical 9 10 application) to a body. Therefore the foam may be used to deliver a drug or any other medicament, may be used 11 12 as a sloughing agent to clean a wound etc, or may be 13 used to provide a sterile covering for a wound etc. 14 15 The present invention also provides the use, separately, of the container, of the composition and of 16 17 the foam described above to produce a wound dressing in 18 the form of a foam sheet. 19 20 In a further aspect, the present invention provides a 21 method of treatment of the human or animal (preferably 22 mammalian) body, said method comprising administering 23 to said body a foam or a foam sheet as hereinbefore 24 defined. Optionally the foam and/or foam sheet may 25 deliver a drug or a medicament to the body. 26 27 The foam and the foam sheet of the present invention 28 are especially suitable for treatment of burns. 29 30 The present invention will now be described with 31 reference to the following examples: 32 33 Unless otherwise stated, the percentage amounts of 34 ingredients are given on a percentage by weight basis. 35

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1	Example 1
. 2	
3	A composition according to the present invention was
4	formed by admixing the following ingredients together:
5	
6	3% Manucol LKX
7	1% Cetrimide
8	80:20 di-ionised water : propan-1,2-diol
9	3% Arglaes (a silver ion releasing glass)
10	
11	A gel composition was formed and autoclaved at
12	approximately 121°C for 15 to 20 minutes. The gel
13	produced was firm but mobile.
14	
15	The gel was foamed using an aerosol canister and a fine
16	celled, highly conformable, thick, creamy foam was
17	produced. There was little slump, little flow, fairly
18	stable, did not go back to a gel when rubbed. The foam
19	was cool and soothing. Once left to dry the flat foam
20	left is still moist, cool sponge. The silver presence
21	was showing.
22	
23	Example 2
24	
25	A composition according to the present invention was
26	formed by admixing the following ingredients together:
27	
28	3% Manucol DMF
29	1% Cetrimide
30	80:20 di-ionised water : propan-1,2-diol
31	
32	A gel composition was formed and autoclaved at
33	approximately 121°C for 15 to 20 minutes. The gel
34	produced was firm but mobile.
35	
36	The gel was foamed using an aerosol canister and a fine

15

1	celled, highly conformable, thick foam was produced.
2	There was no slump or flow. The foam was very stable
3	and did not go back to a gel when rubbed. It was cool
4	and soothing. Once left to dry the flat foam left was
5	still moist, fragile and sponge-like.
6	
7	Example 3
8	
9	A composition according to the present invention was
10	formed by admixing the following ingredients together:
11	
12	3% Keltone
13	1% Cetrimide
14	80:20 di-ionised water : glycerol
15	
16	A gel composition was formed and autoclaved at
17	approximately 121°C for 15 to 20 minutes. The gel
18	produced was firm but mobile.
19	
20	The gel was foamed using an aerosol canister and a fine
21	celled, thick foam was produced. There was no slump or
22	flow. The foam was very stable, had a dry feeling,
23	plasticity, and did not go back to a gel when rubbed.
24	It was cool and soothing. Once left to dry the flat
25	foam was still moist, fragile and sponge-like.
26	
27	Example 4
28	
29	A composition according to the present invention was
30	formed by admixing the following ingredients together:
31	
32	350mls di-ionised water
33	2gms Cetrimide
34	20gms Carboxymethylcellulose
35	40mls Glycerin
36	

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1	A gel composition was formed. The gel produced was
2	very sticky.
3	
4	The gel was foamed using an aerosol canister and a
5	thixotropic, minimum flow, fine cellular foam was
6	formed. It had a thick texture that was virtually
7	unchanged when left overnight.
8	
9	Example 5
10	
11	A composition according to the present invention was
12	formed by admixing the following ingredients together:
13	
14	80mls di-ionised water
15	2gms Cetrimide
16	20mls Glycerin
17	4gms Carrageenan
18	
19	A gel composition was formed. The gel produced was
20	thick and foamed slightly when cetrimide was added
21	(acts like an alginate).
22	
23	The gel was foamed using an aerosol canister and a
24	thixotropic, minimum flow, fine cellular foam was
25	formed. It did not collapse to touch and was difficult
26	to break down into a gel again. After being left
27	overnight it was sticky and non-cohesive.
28	
29	Example 6
30	
31	A composition according to the present invention was
32	formed by admixing the following ingredients together:
33	
34	60mls di-ionised water
35	1.2gms Cetrimide
36	4mls Gelatin

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A gel composition was formed. The gel produced was 1 firm and rigid. Just before foaming 60 mls boiling di-2 ionised water was added and a warm liquid was formed. 3 When pressurised the temperature dropped. 4 5 After the liquid reached the correct temperature within 6 the foaming canister a thick fully expanding foam was 7 It was fine celled and did not break down 8 easily. Initially it was non-thixotropic and then 9 developed into a stable foam. Overnight a firm closed 10 cell sponge with very good handling strength was 11 produced. 12 13 14 Example 7 15 A composition according to the present invention was 16 formed by admixing the following ingredients together: 17 18 80mls di-ionised water 19 20 1ml Tween 80 3qms Keltone 21 22 20mls glycerin 23 A gel composition was formed. The gel produced was 24 25 firm but mobile. 26 The gel was foamed using an aerosol canister and a fine 27 celled, thick, thixotropic foam was produced that 28 29 stabilised very quickly. 30 Example 8 31. 32 A composition according to the present invention was 33 formed by admixing the following ingredients together: 34 35 3% Keltone 36

1	1% Cetrimide
2	80:20 di-ionised water : glycerol
3	4% povidone iodine
4	
5	A gel composition was formed and autoclaved at
6	approximately 121°C for 15 to 20 minutes. The gel
7	produced was firm but mobile.
8	
9	The gel was foamed using an aerosol canister and a fine
10	celled, thin foam was produced that stabilised
11	overnight into a sponge with good handling strength.
12	
13	Example 9
14	A composition according to the present invention was
15	formed by admixing the following ingredients together:
16	
17	3% Keltone
18	1% Cetrimide
19	80:20 di-ionised water : glycerol
20	
21	A gel composition was formed and autoclaved at
22	approximately 121°C for 15 to 20 minutes. The gel
23	produced was firm but mobile.
24	
25	Just before foaming 6g Arglaes powder (ie powdered
26	metal ion releasing glass) was added and the gel was
27	immediately foamed using an aerosol canister. A fine
28	celled, white foam was produced that eventually
29	stabilised into a firm sponge pad.
30	
31	Example 10
32	
3 3	A composition according to the present invention was
3 4	formed by admixing the following ingredients together:
35	
36	3% Keltone

19

1	1% Cetrimide
2	80:20 di-ionised water : glycerol
3	0.1g Chlorohexidine
4	
5	A gel composition was formed and autoclaved at
6	approximately 121°C for 15 to 20 minutes. The gel
7	produced was firm but mobile.
8	
9	The gel was foamed using an aerosol canister and a fine
10	celled, thick foam was produced that stabilised
11	overnight into a sponge pad.
12	
13	Example 11
14	A composition according to the present invention was
15	formed by admixing the following ingredients together:
16	
17	2½% Keltone
18	2½% Carboxymethylcellulose
19	1% Cetrimide
20	80:20 di-water : glycerol
21	
22	The gel composition formed was autoclaved at
23	approximately 121°C for 15 to 20 minutes. The gel
24	produced was firm but mobile.
25	
26	The gel was foamed using an aerosol canister and a fine
27	celled, highly conformable, foam was produced. There
28	was little slump or flow, the foam was fairly stable,
29	cool and soothing. Once left to dry the flat foam
30	sheet was a still moist, cool sponge.
31	
32	Example 12
33	
34	A composition according to the present invention was
35	formed by admixing the following ingredients together:
36	

1	2% Keltone
2	2% Hydroxypropylcellulose
3	1% Cetrimide
4	80:20 di-water : glycerol
5	
6	The gel composition formed was autoclaved at
7	approximately 121°C for 15 to 20 minutes. The gel
8	produced was thick but mobile.
9	
10	The gel was foamed using an aerosol canister and a fine
11	celled foam was produced. There was little slump or
12	flow, the foam was fairly stable, cool and soothing.
13	Once left to dry the flat foam sheet was a still moist,
14	cool sponge.

21

		$\cdot$
1	CLA	<u>ims</u>
2		
3	1.	A formulation for application to a body surface as
4		a foam, said formulation comprising, in admixture
5		or separately, a physiologically acceptable
6		foamable carrier and an active ingredient.
7		
8	2.	A formulation as claimed in Claim 1 wherein said
9		active ingredient is packaged separately to said
10		foamable carrier prior to foaming.
11		
12	з.	A formulation as claimed in either one of Claims 1
13		and 2 wherein said foamable carrier is alginate,
14		carboxymethylcellulose, collagen, a
15		polysaccharide, agar, a polyethylene oxide, a
16		glycol methacrylate, gelatin, a gum, or salts or
17		derivatives of any of these, or mixtures thereof.
18		
19	4.	A formulation as claimed in Claim 3 wherein said
20		foamable carrier is alginate, carboxymethyl-
21		cellulose, the derivatives or salts thereof, or
22		mixtures thereof.
23		
24	5.	A formulation as claimed in any one of Claims 1 to
25		4, wherein said foamable carrier has a molecular
26		weight of from 10,000 to 200,000 kDa.
27		
28	6.	A formulation as claimed in any one of Claims 1 to
29		5, wherein said active ingredient is a silver ion
30		releasing glass composition, chlorhexidine,
31		povidone iodine or cetrimide.
32		
33	7.	A formulation as claimed in any one of Claims 1 to
34		6 further containing a foaming agent.
35		

8. A formulation as claimed in Claim 7 wherein said

1		foaming agent is cetrimide, lecithin, a soap,
2		silicone, a surfactant or the like.
3		
4	9.	A formulation as claimed in any one of Claims 1 to
5		8 in foamed form, wherein said active ingredient
6		is evenly distributed throughout the foam.
7		
8	10.	A formulation as claimed in any one of Claims 1 to
9		9 in the form of a foam sheet.
10		
11	11.	An apparatus to produce a foam for application to
12		a body surface, from a formulation as claimed in
13		any one of Claims 1 to 9, said apparatus
14		comprising:
15		
16		a. a closed container having
17		
18		<ul><li>i) a reservoir containing said foamable</li></ul>
19		carrier;
20		
21		ii) a reservoir containing said active
22		ingredient; and
23		
24		b. foaming means to produce a foam from said
25		foamable carrier.
26		
27	12.	An apparatus as claimed in Claim 11 wherein said
28		foamable carrier and said active ingredient are
29		admixed together and contained within the same
30		reservoir.
31		
32	13.	An apparatus as claimed in Claim 11 wherein said
33		foamable carrier and said active ingredient are
34		contained in separate reservoirs, and wherein said
35		apparatus includes means to evenly disperse active
36		ingredient into the foam.

		23
1	14.	An apparatus as claimed in any one of Claims 11 to
2		13 wherein said foaming means is an aerosol
3		canister.
4		
5	15.	Use of a formulation as claimed in any one of
6		Claims 1 to 10 for medical or veterinary purposes.
7		
8	16.	Use of a formulation as claimed in any one of
9		Claims 1 to 10 as a delivery system for the
10		controlled release of said active ingredient.
11		
12	17.	Use of a foamed formulation as claimed in Claim 9
13		or a foam sheet as claimed in Claim 10 as a wound
14		dressing.
15		
16	18.	A method of treatment of the human or animal body,
17		said method comprising administering to said body
18		a foamed formulation as claimed in Claim 9 or a.
19		foam sheet as claimed in Claim 10.
20		
21	19.	A method as claimed in Claim 18 wherein said
22		foamed formulation or said foam sheet delivers
23		said active ingredient to said body in a
24		controlled release manner.
25		
26	20.	A method as claimed in either one of Claims 18 and
27		19 for treating burns or scalds.
28		
29		

According to International Patent Classification (IPC) or to both national classification and IPC

#### **B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 9247 Derwent Publications Ltd., London, GB; AN 92-384885 & JP,A,04 282 311 (KOIKE KAGAKU)	1,3,6-9, 15-20
Y	see abstract	3,4,6,10
Υ	GB,A,2 207 865 (BIOGAL GYOGYSZERGYAR) 15 February 1989 see claims 1,5,6 see examples 1,2	3,4
	-/	

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
*Special categories of cited documents:  "A" document defining the general state of the art which is not considered to be of particular relevance.  "E" earlier document but published on or after the international filing date.  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified).  "O" document referring to an oral disclosure, use, exhibition or	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention.  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.  "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-
other means  "P" document published prior to the international filing date but later than the priority date claimed	ments, such combination being obvious to a person skilled in the art.  '&' document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
28 February 1996	<b>1</b> 2. 03. <b>96</b>
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Ripswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl. Fam (+ 31-70) 340-3016	Ventura Amat, A

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	manuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
ategory *	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
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